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Commentary

The Canadian government's treatment of scientific process and evidence: Inside the evaluation of North America's first supervised injecting facility

Evan Wood^{a,b,*}, Thomas Kerr^{a,b}, Mark W. Tyndall^{a,b}, Julio S.G. Montaner^{a,b}^a *British Columbia Centre for Excellence in HIV/AIDS, St. Paul's Hospital, Vancouver, Canada*^b *Department of Medicine, Faculty of Medicine, University of British Columbia, Vancouver, Canada*

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Abstract

Although the recommendations of scientific review bodies have traditionally been free of political interference in Canada, there have recently been growing concerns raised about Canada's new federal government's treatment of scientific processes and evidence. This concern is relevant to the scientific evaluation of Canada's first medically supervised safer injecting facility (SIF), which opened in Vancouver in 2003, where illicit injection drug users can inject pre-obtained illicit drugs under the supervision of nurses. This commentary describes what may be a serious breach of international scientific standards relating to the Canadian government's handling of the SIF's scientific evaluation, and the circumstances which eventually led to a moratorium on SIF trials in other Canadian cities. Although the primary focus of this discussion should remain on the health of the people using the SIF, it is hoped that the publication of the information contained in this report will lead to greater public scrutiny of the Canadian government's handling of addiction research and drug policy, and provide lessons for researchers, drug policy-makers, and affected communities in other settings.

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Keywords: Addiction; Supervised injecting; Scientific process; Best evidence; Health policy; Peer review; Political interference**Introduction**

Through the application of evidence-based research, health policies are increasingly being driven by the best available scientific evidence (Kohatsu, Robinson, & Torner, 2004). However, there remain critical areas in public health where the gap between best evidence and public policies persists, and few areas suffer from this concern more than the response to the illicit drug problem (Des Jarlais & Friedman, 1998; Drucker, 1999). This is problematic given that effectively responding to the concerns of HIV transmission, fatal drug overdoses, and crime will require the development of government policies guided by the best available scientific evidence (Des Jarlais & Friedman, 1998).

In 2003, the regional health authority in Vancouver, Canada, successfully applied to the federal government for a legal exemption to pilot North America's first medically supervised safer injecting facility (SIF) (Wood, Kerr, Montaner et al., 2004). This exemption was granted based on the experience of a growing number of international settings which suggests that such initiatives may have unique potential to reduce public illicit drug use while promoting the use of sterile syringes and providing emergency care in the event of overdose (de Jong & Wever, 1999; Freeman et al., 2005; Kimber, Dolan, van Beek, Hedrich, & Zurhold, 2003; Ronco, Spuhler, Coda, & Schopfer, 1996). In order to ensure Canada's compliance with international drug treaties (Malkin, Elliott, & Mcrae, 2003), the SIF's legal exemption to Canada's drug laws was granted on the condition that the programme be subjected to a rigorous scientific evaluation (Wood, Kerr, Montaner et al., 2004).

However, mirroring several reports from the United States where global warming science may have been interfered with

* Corresponding author at: BC Centre for Excellence in HIV/AIDS, St. Paul's Hospital, 608-1081 Burrard Street, Vancouver, BC V6Z 1Y6, Canada. Tel.: +1 604 806 9692; fax: +1 604 806 9044.

E-mail address: uhri@cfenet.ubc.ca (E. Wood).

(Baltimore, 2004; Brumfiel, 2004; Powell, 2002), there has recently been growing concern about Canada's new federal government's treatment of scientific processes and evidence. These concerns have emerged early on in the areas of reproductive technology and stem cell research, and more recently with regard to crime prevention and illicit drugs (Eggertson, 2007; Hebert & Attaran, 2007; Kondro, 2007a). The handling of the evaluation of the SIF in Canada has far-reaching implications, since interventions to address drug use are urgently needed internationally, but some governments and international bodies remain hesitant to support strategies which do not fall under the zero-tolerance umbrella (Small & Drucker, 2007).

This commentary describes the events surrounding the Canadian government's handling of the scientific protocol for the SIF evaluation and the circumstances leading to the halting of a federally funded SIF research programme and a moratorium on Canadian SIF trials.

The scientific SIF evaluation framework

Illicit drug use and the related public health interventions remain subject to considerable debate and controversy (Grinspoon & Bakalar, 1994; Kerr & Wood, 2005; Skolnick, 1994). For example, a body of literature has demonstrated how research findings specific to certain HIV prevention interventions, in particular needle exchange programmes, have been misrepresented by opponents of these strategies (Lurie & Drucker, 1997; Vlahov, 2000). This is despite the fact that a large volume of peer-reviewed studies has demonstrated the effectiveness of needle exchange programmes, and independent scientific reviews by numerous scientific bodies (e.g., the National Institutes of Health in the USA) have endorsed these results (Vlahov, 2000).

The federal exemption for the legal operation of the Vancouver SIF was granted subject to a full scientific evaluation. This was consistent with a Canadian federal task force recommendation that SIF research be prioritized, and accordingly Health Canada sought to fund the research component of the initial 3-year evaluation which began in September 2003. This funding enabled the development of a prospective cohort of individuals recruited from within the SIF, known as the Scientific Evaluation of Supervised Injecting (SEOSI) cohort (Wood, Kerr, Buchner et al., 2004). SEOSI enrolled 1000 SIF users through a randomized recruitment protocol and entails semi-annual monitoring for a large range of health indicators and potential SIF impacts.

Given the challenges associated with HIV prevention research described above (Vlahov, 2000) and the controversial nature of SIF (Gandey, 2003), the Vancouver SIF evaluation was designed to stand up to the highest level of scientific scrutiny. Specifically, the following safeguards were put in place. First, a regional SIF oversight committee was developed which included senior members of all stakeholders groups, including the Chief of the Vancouver Police Depart-

ment and the Provincial Medical Health Officer. Second, in accordance with the transparent reporting of evaluations with nonrandomized designs (TREND) criteria for observational research (Des Jarlais, Lyles, & Crepaz, 2004), it was required that the methodology for the evaluation be subject to external peer review to ensure scientific rigour and publication to ensure scientific openness (Wood, Kerr, Buchner et al., 2004). Finally, it was required that all findings of the evaluation be subject to external peer review and publication prior to dissemination.

Findings from the evaluation

Although the statements of several prominent politicians have implied there is limited scientific support for Insite (Vancouver Sun, 2007), the first 3-year phase of the evaluation yielded a significant array of scientific outputs, including 22 peer-reviewed studies describing the programme's impacts. These publications indicate a range of benefits of the SIF, including but not limited to reduced public injecting and HIV risk behaviour (Kerr, Tyndall, Li, Montaner, & Wood, 2005; Wood, Kerr, Small et al., 2004) and increased uptake of addiction treatment (Wood, Tyndall, Zhang, Montaner, & Kerr, 2007; Wood et al., 2006c). Furthermore, studies seeking to identify potential harms of the SIF found no evidence of negative impacts (Kerr et al., 2006; Wood, Tyndall, Lai, Montaner, & Kerr, 2006). To date, no study has reported negative impacts of the SIF and there has been significant local support for the initiative (Wood, Tyndall, Montaner, & Kerr, 2006).

Given this productivity and the potential for further scientific discovery, in the spring of 2006 the SIF evaluators were invited to prepare a scientific protocol to continue federal support for the SIF's evaluation for an additional 3.5 years. A comprehensive scientific protocol for the continuation of the scientific evaluation of the SIF based on the SEOSI cohort was submitted to Health Canada in May 2006.

The review of the SEOSI protocol

The federal government's own SIF guidance documents state that SIF evaluation protocols must be subject to a transparent and rigorous independent peer review process prior to recommendations being made to the Health Minister. Accordingly, Health Canada officials have confirmed that officials from Canada's Drug Strategy and the Canadian Public Health Agency handled the review process and solicited "national and international experts in the field of interest" to review the protocol. Summary comments contained in these reviews are provided in Table 1 (full reviews are available from the corresponding author).

It has been widely reported in the media that Health Canada bureaucrats subsequently recommended to the Health Minister that the proposal be funded for an additional 3.5

Table 1
Reviewers' comments on the original review of the SEOSI protocol^a

Reviewer 1

- "There has been a strikingly high yield of scientific output during the first two and a half years of this research study, with important scientific communications in high impact journals."
- "Their methodology has been described in peer-referenced scientific journals, which is an unusual course of action for investigators for which they should be commended."
- "The authors are in a good position to continue their previous investigations and achieve results of longer term behaviour patterns, which obviously have not been possible in the period of time available during the funding to date."
- "I would strongly recommend that the research funding support should be provided to enable the continued scientific evaluation."

Reviewer 2

- "Basically, I consider this proposal to be superb and of extremely high importance. The research team has, to date, produced extremely valuable research results. They propose to continue data collection and evaluation, and I have confidence they can do so successfully."
- "In summary, I am in full and enthusiastic support for this proposed research."

Reviewer 3

- "The scientific evaluation is methodologically robust. It is carried out by an internationally renowned team at UBC and the BC Centre for Excellence in HIV/AIDS. In less than three years, this comprehensive and rigorous scientific evaluation has resulted in numerous peer-reviewed publications in major Canadian and international scientific journals."
- "The Canadian scientific evaluation has contributed more to public health than all other international SIS evaluations combined. Despite all the challenges, a prospective cohort study has been set up to measure long term health outcomes."
- "I concur with the scientifically sound findings reported by the research team thus far."

^a Full comments available from the corresponding author.

years. However, on 28 August 2006 and 1 September 2006, two federal law enforcement organisations put forward statements implying that the SIF was unsuccessful and requested the SIF evaluation be halted, without providing any supporting data (Wood, Tyndall, Montaner et al., 2006). Only hours after the Canadian Police Association issued their statement calling for the closure of the SIF on 1 September 2006, Canada's Health Minister, Mr. Tony Clement, issued a press release:

"Initial research has raised new questions that must be answered before Canada's new government can make an informed decision about the future of Vancouver's drug injection site or consider requests for any new injection sites says Federal Health Minister Tony Clement.

"Do safe injection sites contribute to lowering drug use and fighting addiction? Right now the only thing the research to date has proven conclusively is drug addicts need more help to get off drugs,' Minister Clement says. 'Given the need for more facts, I am unable to approve the current request to extend the Vancouver site for another three and a half years.' . . . Health Canada will not entertain any applications for the establishment of additional injection sites in other parts of Canada . . ."

(www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2006/2006_85_e.html)

Subsequently, the investigators received notice that the protocol for the continuation of SEOSI was rejected. No reasons were provided, and a formal request was required before the peer review reports (Table 1) and a description of the peer review process could be obtained. The government's decision to prohibit new SIF research in the rest of Canada was important given that scientists in several Canadian cities, including Victoria and Toronto, had initiated plans to conduct SIF research locally.

Subsequently, the government opened a new competition for new SIF research to ensure its compliance with international drug control treaties (i.e., the SIF could only continue to legally operate as a scientific pilot study). In addition, in a move highly unconventional for scientific grants in Canada, contracts for this research have been awarded only to investigators who agree to refrain from disseminating their findings in any venue (e.g., academic conferences, peer-reviewed publications, the media) until 6 months after the completion of the research and after the current legal exemption has expired (Vancouver Courier, 2007). Legal and ethical consults at the University of British Columbia deemed this requirement to be against university ethical and legal research guidelines, and the SEOSI investigators were precluded from participating (Vancouver Courier, 2007).

Discussion

The events described above should be brought forward for several reasons. First, it appears that the federal government may have interfered with the natural development of evidence-based health policy by disregarding recommendations derived from an independent peer review process conducted by Health Canada and the Canadian Public Health Agency. This is particularly concerning given the unanimously strong peer review of the SIF research protocol and the favourable recommendation supporting continued SIF research in Canada that Health Canada reportedly put forward to the Health Minister's office.

Second, Minister Clement's press release stated that the research has raised "new questions"; however, his office has failed to this date to specifically indicate what these questions are. The release further implied that additional research is necessary, but by interfering with the continuation of the SEOSI cohort, the Minister's office is clearly

compromising the ability to complete such research in favour of smaller projects that must be conducted in secrecy (Vancouver Courier, 2007). The Minister's actions have also undermined the survival of the SEOSI cohort and the related infrastructure that was judged by the external peer reviewers as well positioned to answer important remaining questions.

Third, the Vancouver SIF evaluation has already demonstrated a number of health and community benefits of the SIF, which are consistent with the positive reports from evaluations abroad (de Jong & Wever, 1999; Freeman et al., 2005; Kimber et al., 2003; Ronco et al., 1996). Despite these encouraging results and the positive feedback of the reviewers, the Health Minister not only attempted to interfere with the scientific evaluation of the Vancouver SIF by halting research funding, but also moved directly against the search for new knowledge in this area by declaring a moratorium on any further SIF trials in Canada. This is paradoxical given that the evidence for SIF trials is much improved in comparison to when Vancouver was granted its initial legal exemption, and given that several other cities in Canada have publicly expressed their interest in initiating new SIF research projects.

Finally, it is noteworthy that two federal law enforcement organisations spoke out strongly against continued SIF research at virtually the same time that the federal government made its announcement regarding SIF research in Canada. It is concerning that two publicly funded organisations would coordinate to make such strong statements without providing any data to support their claims, and that these statements were issued immediately before the Health Minister's decision was announced. It is also interesting that the national police force, the Royal Canadian Mounted Police (RCMP), has funded several reviews of SIF research. Interestingly, when the first two reviews endorsed the SEOSI-based evaluation methodology and suggested that SIF are likely a useful tool to reduce drug-related harm, the RCMP issued a press release in an effort to distance itself from the conclusions of these reviews (Wood, Tyndall, Montaner et al., 2006). They subsequently funded a known anti-harm-reduction activist to prepare a third review. This review was recently placed on a website funded by the Drug Free America Foundation and operated by the Institute on Global Drug Policy. Neither of these organisations is a scientific body. The stated goal of the Institute on Global Drug Policy is outlined on the Drug Free America Foundation web site:

“The Institute is charged with creating and strengthening international laws that hold drug users and dealers criminally accountable for their actions. It will vigorously promote treaties and agreements that provide clear penalties to individuals who buy, sell or use harmful drugs. . . . The Institute on Global Drug Policy supports . . . efforts to oppose policies based on the concept of harm reduction”
(www.dfaf.org/globaldrugpolicy.php)

There are several lessons which can be derived from the Canadian experience with SIF evaluation and the government's handling of the research findings. In hindsight, one limitation of the evaluation was that all findings were presented as scientific publications rather than as documents which might be more accessible to the general public and the media (e.g., lay reports). Obviously, greater awareness of the SIF evaluation among national media may have resulted in greater scrutiny of the government's handling of this file.

However, as indicated above, there has been a series of concerns regarding the new Canadian federal government's handling of scientific processes, especially in the areas of reproductive technology and stem cell research and more recently with regard to crime prevention and illicit drugs (Eggertson, 2007; Hebert & Attaran, 2007; Kondro, 2007a, 2007b). In the area of drug policy, as has been well described (Reuter, 2001), the discordance between scientific evidence and the policy response is not uncommon. The reasons that governments commonly advocate ‘get tough’ drug strategies over more scientifically supported measures may stem from the fact that the general population may have little understanding of the lack of scientific support for conventional drug strategies (Blendon & Young, 1998). As such, going against harm-reduction measures and adding support to law enforcement initiatives may help shore up political support, even if it paradoxically leads to an overall worsening of community drug use problems (The Sentencing Project, 2007).

The scientific peer review system is among modern science's greatest strengths and provides an important layer of protection against bias (Burnham, 1990). A foundation of this system is that peer review processes be independent and free of conflict of interest so that policy-makers can utilize the results derived from peer review processes to promote research that is most likely to inform the development of evidence-based health policy, even in instances when such policies are controversial or unpopular (Brumfiel, 2004; Burnham, 1990; Fliesler, 1997; Kotchen, Lindquist, Malik, & Ehrenfeld, 2004; Wessely, 1998). When concerns of political interference or disregard for the peer review process have been suspected, these instances have been met with swift condemnation by the scientific community, since they have the potential to undermine the entire process by which evidence-based policy is derived (Baltimore, 2004; Brumfiel, 2004).

Although the primary focus of this discussion should remain on the health and well-being of the people using the SIF, disregard for the outcome of peer review recommendations represents a serious breach of international scientific standards. It is hoped that the publication of the information enclosed in this report will lead to greater public scrutiny of the new Canadian government's handling of scientific evidence, since the government's rationale for going against the recommendations stemming from this scien-

tific process remains unknown. Ironically, the original grant which had its funding blocked by the federal government was later re-submitted to the Canadian Institutes of Health Research, Canada's national health research organisation which operates independently of the federal government, and was subsequently fully funded. It is hoped that by bringing the above story forward, the Canadian experience will provide lessons for researchers, drug policy-makers, and affected communities in other settings.

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References

- Baltimore, D. (2004). Science and the Bush administration. *Science*, 305(5692), 1873.
- Blendon, R. J., & Young, J. T. (1998). The public and the war on illicit drugs. *JAMA*, 279(11), 827–832.
- Brumfiel, G. (2004). Bush administration dismisses allegations of scientific bias. *Nature*, 428(6983), 589.
- Burnham, J. C. (1990). The evolution of editorial peer review. *JAMA*, 263(10), 1323–1329.
- de Jong, W., & Wever, U. (1999). The professional acceptance of drug use: A closer look at drug consumption rooms in the Netherlands, Germany, and Switzerland. *Int J Drug Pol*, 10, 99–108.
- Des Jarlais, D. C., & Friedman, S. R. (1998). Fifteen years of research on preventing HIV infection among injecting drug users: What we have learned, what we have not learned, what we have done, what we have not done. *Public Health Rep*, 113(Suppl. 1), 182–188.
- Des Jarlais, D. C., Lyles, C., & Crepaz, N. (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *Am J Public Health*, 94(3), 361–366.
- Drucker, E. (1999). Drug prohibition and public health: 25 years of evidence. *Public Health Rep*, 114(1), 14–29.
- Eggertson, L. (2007). New reproductive technology board belies expert selection process. *CMAJ*, 176(5), 611–612.
- Fliesler, S. J. (1997). Rethinking grant peer review. *Science*, 275(5305), 1399.
- Freeman, K., Jones, C. G., Weatherburn, D. J., Rutter, S., Spooner, C. J., & Donnelly, N. (2005). The impact of the Sydney Medically Supervised Injecting Centre (MSIC) on crime. *Drug Alcohol Rev*, 24(2), 173–184.
- Gandey, A. (2003). US slams Canada over Vancouver's new drug injection site. *CMAJ*, 169(10), 1063.
- Grinspoon, L., & Bakalar, J. B. (1994). The war on drugs—a peace proposal. *N Engl J Med*, 330(5), 357–360.
- Hebert, P. C., & Attaran, A. (2007). A plea for transparency in Canada's "new government". *CMAJ*, 176(5), pp. 601, 603
- Kerr, T., Stoltz, J. A., Tyndall, M., Li, K., Zhang, R., Montaner, J., et al. (2006). Impact of a medically supervised safer injection facility on community drug use patterns: A before and after study. *BMJ*, 332(7535), 220–222.
- Kerr, T., Tyndall, M., Li, K., Montaner, J. S., & Wood, E. (2005). Safer injection facility use and syringe sharing in injection drug users. *Lancet*, 366(9482), 316–318.
- Kerr, T., & Wood, E. (2005). The public health and social impacts of drug market enforcement: A review of the evidence. *Int J Drug Pol*, 16(4), 210–220.
- Kimber, J., Dolan, K., van Beek, I., Hedrich, D., & Zurhold, H. (2003). Drug consumption facilities: An update since 2000. *Drug Alcohol Rev*, 22(2), 227–233.
- Kohatsu, N. D., Robinson, J. G., & Torner, J. C. (2004). Evidence-based public health: An evolving concept. *Am J Prev Med*, 27(5), 417–421.
- Kondro, W. (2007a). Conservative government scuttles needle exchange. *CMAJ*, 176(3), 308.
- Kondro, W. (2007b). Health Minister Clement promises crackdown on illicit drug use. *CMAJ*, 177(6), 559.
- Kotchen, T. A., Lindquist, T., Malik, K., & Ehrenfeld, E. (2004). NIH peer review of grant applications for clinical research. *JAMA*, 291(7), 836–843.
- Lurie, P., & Drucker, E. (1997). An opportunity lost: HIV infections associated with lack of a national needle-exchange programme in the USA. *Lancet*, 349(9052), 604–608.
- Malkin, I., Elliott, R., & Mcrae, R. (2003). Supervised injecting facilities and international law. *J Drug Issues*, 33(3), 539–578.
- Powell, K. (2002). Bush climate-change plan gets cool response. *Nature*, 420(6916), 595.
- Reuter, P. (2001). Why does research have so little impact on American drug policy? *Addiction*, 96(3), 373–376.
- Ronco, C., Spuhler, G., Coda, P., & Schopfer, R. (1996). Evaluation for alley-rooms I, II, and III in Basel. *Soc Prev Med*, 41, S58–S68.
- Skolnick, A. A. (1994). 'Collateral Casualties' climb in drug war. *JAMA*, 271(21), 1636–1639.
- Small, D., & Drucker, E. (2007). Closed to reason: Time for accountability for the International Narcotic Control Board. *Harm Reduct J*, 4, 13.
- The Sentencing Project. *A 25 year quagmire: The war on drugs and its impact on American Society*. Available online: http://www.sentencingproject.org/Admin/Documents/publications/dp_25yearquagmire.pdf.
- Vancouver Courier. *Tories put gag on Insite studies*. Friday October 5, 2007.
- Vancouver Sun. *Friday October 5, 2007. Insite not the best strategy, PM says*.
- Vlahov, D. (2000). The role of epidemiology in needle exchange programs. *Am J Public Health*, 90(9), 1390–1392.
- Wessely, S. (1998). Peer review of grant applications: What do we know? *Lancet*, 352(9124), 301–305.
- Wood, E., Kerr, T., Buchner, C., Marsh, D. C., Montaner, J. S., & Tyndall, M. (2004). Methodology for evaluating Insite: Canada's first medically supervised safer injection facility for injection drug users. *Harm Reduction J*, 1(1), 9.
- Wood, E., Kerr, T., Montaner, J. S., Strathdee, S. A., Wodak, A., Hankins, C. A., et al. (2004). Rationale for evaluating North America's first medically supervised safer injecting facility. *Lancet Infect Dis*, 4, 301–306.
- Wood, E., Kerr, T., Small, W., Li, K., Marsh, D., Montaner, J. S., et al. (2004). Changes in public order after the opening of a medically supervised safer injecting facility for illicit injection drug users. *CMAJ*, 171(7), 731–734.

- Wood, E., Tyndall, M. W., Lai, C., Montaner, J. S., & Kerr, T. (2006). Impact of a medically supervised safer injecting facility on drug dealing and other drug-related crime. *Subst Abuse Treat Prev Policy, 1*, 13.
- Wood, E., Tyndall, M. W., Montaner, J. S., & Kerr, T. (2006). Summary of findings from the evaluation of a pilot medically supervised safer injecting facility. *CMAJ, 175*(11), 1399–1404.

- Wood, E., Tyndall, M. W., Zhang, R., Montaner, J. S., & Kerr, T. (2007). Rate of detoxification service use and its impact among a cohort of supervised injecting facility users. *Addiction, 102*(6), 916–919.
- Wood, E., Tyndall, M. W., Zhang, R., Stoltz, J. A., Lai, C., Montaner, J. S., et al. (2006). Attendance at supervised injecting facilities and use of detoxification services. *N Engl J Med, 354*(23), 2512–2514.